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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,442	07/18/2003	Tae-Wan Kim	66195/JPW/AJM/JCS	3560

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,442	KIM ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 and 20-22, drawn to an isolated CD44 fragment and an article of manufacture, classified in Class 530, subclass 324-330.

II. Claims 6-8, drawn to an antibody which specifically binds to the CD44 fragment; classified in Class 530, subclass 387.3, and 391.1.

III. Claims 9-10, drawn to a method for determining whether an agent increases the amount of CD44 fragment formed in a $CD44^+$ cell comprising contacting the $CD44^+$ cell with the agent, determining the amount of γ-secretase-generated CD44 fragmetn present in the $CD44^+$ cell; classified in Class 435, subclasses 7.2.

IV. Claim 11, drawn to a method for increasing the amount of CD44 fragment formed in a CD44+ cell, which method comprises introducing into the cell γ-secretase, classified in Class 435, subclasses 7.2.

V. Claim 11, drawn to a method for increasing the amount of CD44 fragment formed in a CD44+ cell, which method comprises introducing into the cell γ-secretase agonist, classified in Class 435, subclasses 7.2.

VI. Claim 11, drawn to a method for increasing the amount of CD44 fragment formed in a CD44+ cell, which method comprises introducing into the cell γ-secretase **and** γ-secretase agonist, classified in Class 435, subclasses 7.2.

VII. Claims 12-15, drawn to a method for determining the amount of CD44 fragment in a sample comprises contacting the sample with the antibody that binds a CD44 fragment, classified in Class 435, subclasses 7.1.

VIII. Claim 18, drawn to a method for treating a subject afflicted with a CD44-associated disorder comprising administering to the subject γ-secretase, wherein the CD44-associated disorder is cancer , classified in Class 424, subclasses 185.1.

IX. Claim 18, drawn to a method for treating a subject afflicted with a CD44-associated disorder comprising administering to the subject γ-secretase agonist, wherein the CD44-associated disorder is cancer, classified in Class 424, subclasses 185.1.

X. Claim 19, drawn to a method for treating a subject afflicted with a CD44-associated disorder comprising administering to the subject γ-secretase, wherein the CD44-associated disorder is streptococcal invasion, classified in Class 424, subclasses 185.1.

XI. Claim 19, drawn to a method for treating a subject afflicted with a CD44-associated disorder comprising administering to the subject γ-secretase agonist, wherein the CD44-associated disorder is streptococcal invasion, classified in Class 424, subclasses 185.1.

XII. Claim 18, drawn to a method for treating a subject afflicted with a CD44-associated disorder with CD44 fragment, wherein the CD44-associated disorder is cancer, classified in Class 424, subclasses 185.1.

XIII. Claim 19, drawn to a method for treating a subject afflicted with a CD44-associated disorder with CD44 fragment, wherein the CD44-associated disorder is streptococcal invasion,, classified in Class 424, subclasses 185.1.

Claim 16 links inventions VIII-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 16. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Similarly, claim 17 links inventions XII-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 17.

2. Groups I and II are different products. Polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups III-XIII are different methods. Various methods for determining, various methods for increase and various method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups I/(XII and XIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the CD44 fragments of Group I can be used for affinity purification, in addition to the various methods recited.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 27, 2005

Maher Haddad

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Patent Examiner
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